May 31, 2011

The Honorable Christine Varney
Assistant Attorney General
Antitrust Division
United States Department of Justice
950 Pennsylvania Avenue, N.W.
Washington, DC 20530

The Honorable Jon Leibowitz
Chairman
Federal Trade Commission
600 Pennsylvania Avenue, N.W.
Washington, DC 20580

Re: Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program, Matter V100017

Dear Assistant Attorney General Varney and Commissioner Leibowitz:

On behalf of the Kansas Hospital Association, we are providing comments to your respective agencies on the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare ACO/Shared Savings Program. We very much appreciate the antitrust agencies' effort to work cooperatively with other federal agencies to craft the proposed legal and regulatory framework.

CHANGES TO THE "GUIDANCE" ARE NEEDED

The primary question posed by the agencies to prospective ACO applicants in the Statement is: "[w]hether and, if so, why, the guidance in the proposed policy statement should be changed." In order for the Medicare ACO program to achieve its ambitious goal of helping to transform the way health care services are paid for and delivered to benefit patients and communities, the antitrust agencies must make fundamental changes in their approach. In its current form, the Statement serves as a significant barrier to participation in the Medicare ACO Shared Saving Program and does not provide the guidance needed to spur adoption of and continued innovation in clinical integration beyond the Medicare program.

We urge your agencies to revise the Statement by providing for comment from all those affected, as well as more user-friendly guidance on how the agencies will analyze clinically integrated organizations for anti-trust risk under the rule-of-reason. Guidance should not be a prerequisite for participation in the Medicare ACO program, instead the agencies should continue to respond to concerns as they arise in the marketplace. Rural settings should be given particular consideration through means such as broadening the proposed rural exception to the market share threshold. The agencies should also provide for a streamlined process for clinically integrated organizations to receive more specific advice that works in sync with the Centers for Medicare & Medicaid Services' Shared Savings Program application process.

THE STATEMENT LACKS RULE-OF-REASON ANALYSIS SPECIFICS

One of the most useful features of the Statement was assurance that Medicare ACOs would be reviewed by the antitrust agencies under the rule-of-reason, balancing pro-competitive potential against anticompetitive risk. Specific guidance from the agencies on how that analysis would be applied would assist hospitals and other providers in forming and operating such clinically integrated organizations.

The hospital field has long sought guidance from the antitrust agencies on clinical integration, similar to that in the Statements of Antitrust Enforcement in Health Care. It was the 1996 Statements that first broadened the concept of legitimate provider integration to include clinical integration. The agencies have since declined repeated calls to provide guidance in a similar manner. The Medicare ACO program provides an opportunity for the antitrust agencies to issue such guidance focused on how the agencies will analyze ACOs and similarly clinically integrated organizations under the rule-of-reason.

THE PROPOSED FORMULAS SHOULD BE ABANDONED

The Statement proposes an untested and problematic formula to determine the shares of each prospective ACO participant in its Primary Service Area (PSA). Shares must be calculated for *each* common service to be provided by *each* participating hospital and doctor (or group of doctors) within *each* provider's PSA. PSA is defined as the lowest number of contiguous zip codes from which the provider draws at least 75 percent of its patients. Serious concerns with this new formula include:

- Calculating PSA shares on the basis of Medicare fee-for-service data is likely to be unreliable and will be practically unavailable for any service or medical specialty that does not routinely provide services to Medicare patients, for example obstetrics and pediatrics. The data will also overstate the shares of providers who care for large numbers of Medicare patients and understate the shares of those who restrict their practices to commercially-insured patients. Even where Medicare fee-for-service data might be available, it will be extremely difficult for physicians to pull zip code data and match it with billing records to obtain the services provided.
- Calculating PSA shares on the basis of contiguous zip codes likely will be burdensome and costly and require substantial judgment calls.
- The Stark law requires that compensation for health care providers be fixed in advance and paid only for hours worked. The statute could be implicated if a hospital compensates physicians by organizing and paying for the costly analysis required to determine physician PSA shares. There is no indication in the Statement, or the related document discussing possible CMS/OIG fraud and abuse waivers, that a waiver for such activities and expenses is being considered.

MANDATORY REVIEW SHOULD NOT BE REQUIRED

Under the proposed Statement, any prospective Medicare ACO applicant receiving a PSA score of 50 percent or above for any service or specialty is subject to *mandatory* review by one of the antitrust agencies. This is true even if the score is for a non-Medicare service, such as pediatrics, and even if the ACO applicant's PSA share is well below 50 percent for the vast majority of services provided.

Mandatory review is not confined to the specific service(s) over 50 percent, but will instead subject the entire Medicare ACO applicant to antitrust scrutiny. Therefore in order to defend an ACO application, a prospective applicant with even a single PSA above 50 percent would need to submit a large number of

documents (that do not overlap with those required by other agencies) and obtain a time-consuming and expensive analysis from an antitrust practitioner.

This approach inappropriately delegates to the antitrust agencies the authority to determine which ACO will be permitted to apply for the Medicare Shared Saving Program based on concerns about whether the ACO could impact price competition in the private sector. This concern seems particularly misplaced because the application at issue would be to participate in a program in which there is no price competition, given the terms, conditions and reimbursement are dictated solely by a federal agency.

The antitrust agencies could make a positive contribution by developing a truly streamlined process (90 days or less) that *allows* prospective ACO applicants to obtain antitrust guidance at the same time CMS is reviewing the application. Such a process would also aid other clinically integrated organizations.

OTHER CONCERNS TO BE ADDRESSED

- The rural exception is too narrow. A larger share of providers not exclusive to any one ACO should be allowed under the exception due to the unique challenges of providing access to and continuity of care in rural areas. It is potentially restrictive to require nonexclusive participation from physicians from *each* specialty and/or *each* rural hospital in order to qualify for the safety zone.
- The promise of a safety zone is seriously compromised if it is too low and exclusivity is not permitted. The safety zone of 30 percent or less should be increased to at least 35 percent. Qualifying for the safety zone should not require participants to contract or even be able to contract with other ACOs. Exclusivity will likely be an important tool to ensure that a Medicare ACO is able to meet the quality reporting and health information technology meaningful use requirements in the proposed CMS rule.

We appreciate the collaboration among the agencies that went into the Proposed Statement of Antitrust Enforcement Policy. However, in its current form it poses unnecessary barriers to Medicare ACO formation and operation. We hope the antitrust agencies will take this opportunity to substitute for the Statement a streamlined and voluntary process to obtain antitrust related guidance from the agencies.

Sincerely,

Thomas L. Bell
President and CEO

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